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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,831	07/11/2001	Thomas J. Maginot	22220-06167	1578

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,831

Applicant(s)

MAGINOT, THOMAS J.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 121-123, 125, 127, 129-133, 136, 140, 142, 143, 164, 165, 425-428, 432 and 434-436 is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 70,71,73,75-78,80-82,84-86,88,90-94, 96,98, 101, 102,104-109,114, 117, 119,121-123, 125, 127, 129-134, 136-140,142-143,146,148,152-153,155-157,159-162,164-166 and 425-436.

Continuation of Disposition of Claims: Claims rejected are 70,71,73,75-78,80-82,84-86,88,90-94, 96,98, 101, 102,104-109,114, 117, 119, 134, 137-139,146,148,152-153,155-157,159-162,166, 429-431, and 433.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2005 has been entered.

It is noted that claim 82 was not amended properly in that lines 14-16 should have been entirely underlined, except for the strikethrough portions of the text, in that these limitations were new to claim 82. Furthermore, the amendment to claim 82 eliminated a key limitation on line 6 (see previous claim 80). For this reason, the Applicant is warned about using proper amendment practice. Future editorial errors may result in the amendment being held non-compliant with 37 CFR 1.121.

Claim Objections

Claim 70 is objected to because of the following informalities:

On lines 2-3 of claim 70, the language "and (ii) flange portion" is grammatically awkward. The Examiner suggests inserting the word "a" after "(ii)" in order to overcome this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 77, 119, 134, and 161 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The language "at least four arms" lacks original support in that it encompasses a great number of arms up to an infinite number. Rather, the specification was originally limited to "a number of springs other than four can be used." This language does not support an open-ended range. The Examiner suggests replacing "at least four arms" with ---four arms or a number of arms other than four--- (as used in the specification) in order to overcome both Section 112 rejections.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 77, 119, 134, and 161 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The open ended range of "at least four arms" is indefinite because it is unclear what constitutes an upper limit, in any, of the claim scope; see MPEP 2173.05(c) II that is incorporated herein by reference. The Examiner suggests replacing "at least four arms" with ---four arms or a number of arms other than four--- (as used in the specification) in order to overcome both Section 112 rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 70, 71, 73, 75-78, 80-81, 85-86, 88, 90-94, 96, 98, 101, 102, 104-107, 109, 137-139, 146, 148, 152-153, 155-157, 159-162, 166, 431, and 433 are rejected under 35 U.S.C. 102(e) as being anticipated by Piplani et al (US 5,489,295). Piplani anticipates the claim language where the locating step is not specifically disclosed thereby but inherent thereto because the graft is shown within the delivery device in Figures 9 to 19. The arms as claimed are met by the legs or struts of a Piplani as attachment means (126), the alignment step as claimed is performed in Figures 9 and 10 of Piplani where the graft is inserted into the hole (226). The attachment means self-expands so the claimed spring action or resiliency is met; see column 9, lines 7-12. The terminology “radially about” is interpreted broadly as encompassing “around” or “near” not necessarily “over.” The terminology “extravascularly” aligning and locating the flange portion inherently occurs in Piplani as the graft thereof is aligned and advanced through the arteriotomy; note what occurs between the steps shown in Figures 9 and 10.

Regarding claim 71 and the other claims that set forth a flange portion, the claimed flange portion is made up coil springs (203) and/or hook-like elements (207) which constitute a projecting rim, edge, or collar to provide a place to attach other objects; i.e. a flange. Since the flange portion is made up of coil springs (203) and/or hook-like elements (207), it can be said that the arms (204) and (206) are within the flange portion. Even if one could argue that the arms (204) and (206) of Piplani are not within the coil springs (203), they are certainly with the hook-like elements (207), which is an alternative interpretation in the rejection. In other words, the flange portion is the collective total of the hook-like elements (207) and coil springs (203). Furthermore, "an interior wall" can be the wall inside the delivery device and a portion or all of the arms can extend through the arteriotomy.

Regarding claims 109 and 153, some additional advancing of the graft is not precluded by the present claim language such that the claimed method is reads on what is disclosed by Piplani.

Claims 108, 114, 117, and 119 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaster et al (US 5,366,462) as evidenced by Balog et al (US 4,937,039). Kaster anticipates the claim language where the 316 stainless steel thereof is inherently resilient as claimed as evidenced by Balog; see claims 30 and 39 thereof. For this reason, Kaster meets all the claim limitations; see the figures and column 5, lines 54-66.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 429 and 430 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaster et al (US 5,366,462) in view of Kaster (US 4,366,819). Kaster ('462) meets the claim method except Kaster ('462) fails to disclose utilizing the device by anastomotically connecting the bypass graft to the aorta as claimed. However, Kaster ('819) teaches that it was known to the art to anastomotically connect the aorta to the coronary artery with a similar anastomotic device; see the figures and column 10, lines 42-54. Therefore, it is the Examiner's position that it would have been obvious to utilize the Kaster ('462) device to connect the graft thereof to an aorta so that the method of Kaster ('819) could be performed for a patient in need thereof with the ease of use demonstrated by Kaster ('462).

Allowable Subject Matter

Claims 121-123, 125, 127, 129-133, 136, 140, 142, 143, 164, 165, 425-428, 432, and 434-436 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments filed October 25, 2005 have been fully considered but they are not persuasive.

Applicant argues that various features of the claims are not disclosed by Piplani. However, upon review of Piplani (particularly Figures 9, 10, and 11), the Examiner concluded that all the claimed features are present therein such that the claim language is at least read of what is disclosed by Piplani. The Examiner has added further

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explanations to the rejection to explain how the method of Piplani reads on the claimed method.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilic
Primary Examiner
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